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OCT 26 2004

Attorney Docket No.: 19626-0112 (45454-259755)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Reiko M. Nakamura

Serial No.: 09/877,802

Filed: June 6, 2001

For: METHODS AND COMPOSITIONS FOR  
DETECTION AND DIAGNOSIS OF  
INFECTIOUS DISEASES

Art Unit: 1641

Examiner: Gabel, G.

**DECLARATION UNDER 37 C.F.R. §1.132 BY REIKO M. NAKAMURA**

1. I, Reiko M. Nakamura, Ph.D., the sole inventor of the above-referenced U.S. patent application, do hereby declare that I received a Bachelor of Art degree and a Doctor of Philosophy degree in zoology from Tokyo Kyoiku University in 1958 and 1963, respectively, and currently work as a consultant for Sequella Inc. in the United States.

2. The pending claims of the above-referenced U.S. patent application have been rejected under 35 U.S.C. 102(a) in view of Japanese Patent Application No. JP 09206092. The referenced Japanese patent application lists Katsuhide Kawajiri, Ikuro Honda, Ichiro Toida and me as co-inventors.

3. I declare that Katsuhide Kawajiri, Ikuro Honda, Ichiro Toida did not discover the subject matter claimed in the above-identified U.S. patent application. I am the sole inventor of the subject matter disclosed in the above-identified U.S. patent application. Katsuhide Kawajiri, Ikuro Honda and Ichiro Toida were working in my laboratory at the time the subject matter of the referenced Japanese patent application was being investigated. For the duration of that investigation and pursuant to my supervision and direction, Katsuhide Kawajiri and Ikuro Honda conducted various experiments, which were directed to the isolation of proteins from BCG short culture. Ichiro Toida supported

Declaration Under 37 C.F.R. §1.132 by Reiko M. Nakamura  
October 25, 2004  
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the investigation as a manager of Japan BCG Laboratory. At no time did Katsuhide Kawajiri, Ikuro Honda or Ichiro Toida make any inventive contribution to the subject matter claimed in the above-referenced patent application.

4. As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application, or any patent issued thereon.

Dated: OCT 25, 2004

Reiko M. Nakamura

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